IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

In re.:	MDL No. 1953
Heparin Product Liability Litigation	Case No. 1:08hc600000
	This Document Applies to All Cases
ROBERT YEAZEL, JR., as Executor of the Estate of CAROL ANN YEAZEL,	Case No. 1:09hc60186
Plaintiff,	ORDER
v.	
BAXTER HEALTHCARE CORP., et al.	
Defendants.	

Pending are Motions to Exclude Expert Testimony of Dr. Clifford Siporin (Doc. 34), Dr. Suzanne Parisian (Doc. 38)[1], and Paul Midler (Doc. 464) filed by defendants American Capital Ltd. (ACAS), Baxter Healthcare Corp. and Baxter International, Inc. (Baxter) and Scientific Protein Laboratories, LLC (SPL). For the reasons that follow, defendants' motions shall be granted in part an denied in part.

Background

This multidistrict litigation is a products liability action arising out of the manufacture and sale by defendants of contaminated Heparin. The plaintiffs allege that the use of contaminated Heparin caused a myriad of adverse allergic-type responses leading to serious injuries, and in some cases, death.

[1]Docs. 34 and 38 filed in 1:09hc60186.

Heparin is a commonly used blood thinner. Heparin acts as an anticoagulant by decreasing the clotting ability of blood, thereby preventing formation of clots and stopping the growth of already existing clots. It has been marketed in the United States for nearly seventy years and is used in a variety of clinical settings, including during kidney dialysis and cardiac procedures, and for treatment or prevention of serious medical conditions, including pulmonary embolis and deep vein thrombosis. Over one million multi-dose vials of Heparin are sold per month in the United States. Baxter supplies about half of the Heparin sold in this country.

In late December, 2007, the FDA and Baxter received over 350 adverse event reports associated with the use of Heparin. The FDA characterized this as a marked increase from the number of reports associated with Heparin use normally received in a similar time period. The FDA determined that these adverse events were associated with Baxter Heparin contaminated with an unknown agent.

On January 17, 2008, Baxter recalled nine multi-dose lots, and on February 29, 2008, Baxter recalled all its Heparin single and multi-dose vials and HEP–LOCK flush products.

A period of intense effort to determine the nature and source of the contaminant ensued. This resulted in the discovery that Heparin's active pharmaceutical ingredient (API), which Baxter obtained from Chinese suppliers and incorporated into certain categories of Heparin products, contained Over-Sulfated Chondroitin Sulfate (OSCS). OSCS is a synthetic compound with anticoagulant properties that acts as a Heparin mimic.

Litigation followed in both state and federal courts. On June 6, 2008, the Judicial Panel on Multidistrict Litigation transferred federal Heparin products liability cases to this court for

consolidated pretrial proceedings. The pending motions involve challenges to proposed expert testimony.

Discussion

Plaintiffs' experts Dr. Siporin, Dr. Parisian, and Mr. Midler are prepared to offer generic liability testimony about Defendants' manufacturing, production, testing, distribution, marketing, and post-marketing surveillance of Heparin. Defendants contend these opinions are beyond the scope of these witnesses' expertise, unreliable, irrelevant, prejudicial, and exceed the scope of permissible expert testimony. Defendants seek to preclude all testimony by these individuals.

Standards for Admissibility Under Fed. R. Evid. 702

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may pursuant to Fed. R. Evid. 702 present opinion testimony as to facts in issue if: 1) the testimony is based upon sufficient facts or data; 2) the testimony is the product of reliable principles and methods; and 3) the witness has applied the principles and methods reliably to the facts of the case.

In *Daubert v. . Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the Supreme Court prescribed the standard for admitting expert scientific testimony. The Court held that trial judges should determine "whether the reasoning or methodology underlying the testimony is scientifically valid and ... whether that reasoning or methodology properly can be applied to the facts in issue." *Id.* at 592-593. The Court has expanded the scope of its *Daubert* principles to technical or other specialized knowledge, such as that at issue in the some of the pending motions. *Kumho Tire Co. v.. Carmichael*, 526 U.S. 137 (1999).

Under *Daubert*, trial judges are to assess the relevance and reliability of expert testimony. 509 U.S. at 592-593. The relevance requirement ensures that there is a proper "fit" between the testimony and issue at trial. *See generally U.S. v. Bonds*, 12 F.3d 540, 555 (6th Cir. 1993). The reliability requirement focuses on the methodology and principles underlying the testimony. *Id*. at 556. *Daubert* places the burden of proof as to admissibility on the party offering expert testimony. 509 U.S. at 592 n.10.

The Court in *Daubert* listed several factors for consideration in assessing the reliability of expert testimony. *Id*. The test of reliability is, however, "'flexible, and *Daubert* 's list of specific factors neither necessarily nor exclusively applies to all experts or in every case." *Kumho Tire*, *supra*, 526 U.S. at 140. "[W]hether *Daubert* 's specific factors are, or are not, reasonable measures of reliability in a particular case is a matter that the law grants the trial judge broad latitude to determine." *Id.* at 153.

Different approaches may be permissible, but the focus must be on the principles and methodologies on which the expert's opinion is based, and not on the merits of the expert's conclusions. *Daubert*, 509 U.S. at 594-595 n.12; *Bonds*, *supra*, 12 F.3d 540, 556 (6th Cir.1993) (district courts "are not to be concerned with the reliability of the conclusions generated by valid methods, principles and reasoning.").

Described by *Daubert* as a "gatekeeper," the judge is to determine "whether the reasoning or methodology . . . is scientifically valid and . . . whether that reasoning or methodology properly can be applied to the facts in issue." 509 U.S. at 592-93. The Court emphasized, however, that "'nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.' " *Id*. at 157

(quoting *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). In short, "[p]roposed testimony must be supported by appropriate validation – i.e., "good grounds," based on what is known. *Pride v. BIC Corp*., 218 F.3d 566, 577 (6th Cir. 2000) (quoting *Daubert.* 509 U.S at 590).

Lastly, case law after *Daubert* demonstrates that "rejection of expert testimony is the exception rather than the rule." *In re Gadolinium-Based Contrast Agents Products Liab. Litig*., 2010 WL 1796334, * 2 (N.D. Ohio), *opinion modified on reconsideration*, 2010 WL 5173568 (N.D. Ohio). The trial judge's role as gatekeeper "is not intended to serve as a replacement for the adversary system." *Id*. (quoting *U.S. v. 14.38 Acres of Land Situated in Leflore County, Miss*., 80 F.3d 1074, 1078 (5th Cir.1996)). "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 595.

1. Dr. Clifford Siporin

Dr. Siporin, a microbiologist specializing in drug development, has worked in the pharmaceutical industry for more than thirty years. Currently, he is the principal, chief consultant and founder of a consulting firm specializing in pharmaceutical development and manufacturing processes in Asia and the United States.

Prior to founding his consulting firm, Dr. Siporin held various executive and management level positions in the pharmaceutical industry. Most recently, he served as Vice President of Drug Development at G.D. Searle & Co., where his responsibilities included overseeing clinical development, international marketing, and regulatory affairs. He has also held similar high level positions at Warner Lambert Co./Parke Davis and Phizer, Inc.

Dr. Siporin is knowledgeable about API manufacturing, site auditing, and medical and regulatory affairs. His firm provides advice in Good Manufacturing Practice (GMP) compliance auditing, manufacturing, licensing, and other quality assurance functions.

Dr. Siporin expects to testify that: 1) Baxter and SPL could have prevented the contamination of Baxter's Heparin products by establishing appropriate impurity specifications, an impurity profile for heparin API, and conducting quality testing; 2) Baxter's Heparin products were defective and unreasonably dangerous when introduced into the stream of commerce; 3) SPL and Baxter failed to exercise reasonable care to assure the purity and safety of their products; 4) Baxter and SPL ignored numerous "red flags" indicating quality control problems with Chinese crude heparin and therefore, consciously disregarded the rights and safety of patients; and 5) Baxter and SPL "took advantage" of the fact of the FDA's mismanagement of its drug inspection program and its failure to audit SPL's Chinese facility.

Defendants seeks to exclude Dr. Siporin's opinions in their entirety on the basis that his opinions exceed the scope of his expertiese, are unreliable and irrelevant.

With regard to the scope of Dr. Siporin’s expertise, defendants argue that he can not opine about analytical-chemistry methods, such as NMR spectroscopy, because he is not a chemist. Defendants also assert he is unqualified to offer opinions on manufacturing in China because he has never done business in China and has no first-hand experience with Chinese quality control issues other than in this case.

Defendants contend that Dr. Siporin's opinions are unreliable and irrelevant because they are not supported by analysis or validation and are simply factual summaries followed by

unsupported conclusions. Dr. Siporin has, according to Defendants, made factual errors and failed to consider directly relevant documents and contradictory information.

Finally, Defendants argue that Dr. Siporin offers impermissible "ultimate issue" testimony, thereby usurping the jury's function and intruding on the role of the jury and the court.

To qualify as an expert under Rule 702, a witness must establish his or her expertise by reference to "knowledge, skill, experience, training, or education." *Pride*, *supra*, 218 F.3d at 577. "The issue with regard to expert testimony is not the qualifications of a witness in the abstract, but whether those qualifications provide a foundation for a witness to answer a specific question." *Berry v. City of Detroit*, 25 F.3d 1342, 1351 (6th Cir. 1994).

Under the Federal Rules of Evidence, a court concerns itself, when determining the qualifications of an expert, solely with whether the expert's knowledge of the subject matter is such that his opinion will likely assist the trier of fact in arriving at the truth. The weight of the expert's testimony must be for the trier of fact. *Mannino v. Int'l Mfg. Co.*, 650 F.2d 846, 851 (6th Cir. 1981).

I find Dr. Siporin qualified to testify about the processes involved in the manufacture of safe drugs, including what quality control measures a pharmaceutical company should take to ensure that its product will be safe once it enters the marketplace. His extensive relevant experience as a research scientist, consultant, and pharmaceutical executive in drug development, manufacturing and quality control provide a foundation for him to answer questions about these processes.

I conclude Dr. Siporin may testify about appropriate supply chain protocols a pharmaceutical company should implement in dealing with its suppliers. He may tell jurors how a company should investigate its suppliers and their suppliers' sources, precautions needed to ensure the quality of raw

ingredients throughout the supply chain, and what steps a company must take to avoid contamination and adulteration.

Dr. Siporin may also testify about the need to test ingredients and final products to confirm compliance with regulatory standards for purity and safety. The fact that Dr. Siporin, as Defendants contend, may not know the specific mechanics of a particular testing method is irrelevant. Plaintiffs will call him to testify about steps a company should take to properly and safely produce drugs; they do not call him to testify about the mechanics and methods of specific tests. I find that he is qualified to testify on the broader subjects as Plaintiffs propose.

Likewise, Dr. Siporin can testify about additional or special precautions that an American company should take when dealing with foreign suppliers using foreign raw ingredient supply sources. He can talk about the attendant risks and consequences of relying on overseas suppliers and what an American company should do to avoid those risks.

Though Dr. Siporin may testify generally about dangers and safeguards relating to foreign sources of supply for American drug companies, he has insufficient experience to testify specifically about such dangers and safeguard as to Chinese suppliers. Thus, he may not testify about other instances of Chinese products being tainted, adulterated or contaminated, such as cough syrup and dog food. His sparse and random anecdotal knowledge does not qualify him as an expert about specific problems involving Chinese suppliers.

As so limited, I also find Dr. Siporins' opinions reliable. Generally, an experts' opinions meet the reliability threshold when "whether basing testimony on professional studies or personal experience, [the expert] employs in the courtroom the same level of intellectual rigor that characterizes the practice in the relevant field." *Jahn v. Equine Servs., PSC*, 233 F.3d 382, 388 (6th

Cir.2000) (citing *Kumho Tire*, 526 U.S. at 152). "When assessing the reliability of opinions a witness seeks to provide as expert testimony, "the law grants a district court the same broad latitude when it decides how to determine reliability as it enjoys in respect to its ultimate reliability determination."" *U.S. v. Gallion*, 257 F.R.D. 141, 149 (E.D. Ky. 2009) (quoting *Kumho Tire*, 526 U.S. at 142). "The reliability requirement . . . should not be applied too strictly. Helpfulness to the trier of fact remains the ultimate touchstone of admissibility." *Holbrook v. Lykes Bros. S.S. Co.*, Inc., 80 F.3d 777, 784 (3d Cir. 1996).

Dr. Siporin's proposed testimony is based on "good grounds" and will be helpful to the jury. He will not simply be reading documents or drawing vast generalizations, instead he will tell the jury how, in his opinion, in light of his extensive relevant experience with American pharmaceutical companies, a company should go about the business of obtaining safe supplies and producing a safe final product. He will place facts in the context of the standard of care applicable to pharmaceutical companies.

The Defendants' concerns about the factual basis of Dr. Siporin's opinions go to credibility and weight and are issues for cross-examination, not reasons to preclude his opinions.

Dr. Siporin thus may testify as to the Defendants' actions or inactions that may have led to production and distribution of adulterated heparin and how they could have avoided this outcome.

Dr. Siporin may not, however, "tell the jury what result to reach" on ultimate questions of liability. *Woods v. Lecureux*, 110 F.3d 1215, 1220 (6th Cir. 1997). Although Dr. Siporin's opinion may "embrace[ ] an ultimate issue to be decided by the trier of fact[,]" the issue embraced must be a factual one." *Berry, supra*, 25 F.3d at 1353 (quoting Fed.R.Evid. 704(a)).

Dr. Siporin can testify, if a proper foundation is laid, that the Defendants' quality control measures were inadequate. He also could testify regarding what he believes to be the consequences of those quality control failures.

He may not testify, however, that the conduct of Defendants indicated that they "consciously disregarded" the welfare of patients receiving their products. Nor may he testify about the knowledge, motivations, intent or purposes of Defendants or their employees.

Based on the foregoing, Defendants' motion as to Dr. Siporin shall be granted in part and denied in part.

2. Dr. Suzanne Parisian

Dr. Suzanne Parisian is a medical doctor board-certified in anatomic and clinical pathology. She also has a Masters Degree in Biology. She has been a general practitioner and President of Mountain Emergency Physicians. From 1991 to 1995, she served as a Commissioned Officer in the United States Public Health Service, achieving the rank of Lt. Commander. During this time she was assigned to the Center for Devices and Radiological Health at the FDA where she served as a Medical Officer. As an FDA Medical Officer, she provided regulatory support to both FDA's Office of Compliance and Office of Device Evaluation from 1991 to 1992, where her responsibilities included health hazard and risk assessment (she presided over 162 health risk assessments), Safety Alerts and physician and layperson communications, review of Adverse Event Reports (AERs) and medical literature, and review of product labeling, promotions, advertising, and corporate records.

Regarding post-market surveillance, Dr. Parisian participated in 1993 with the FDA's Office of Compliance and General Counsel in mandatory nationwide product recalls requiring review of

manufacturing records, product labeling, product complaints, and AERs. She also trained new medical officers and scientific reviewers in application, clinical trial and labeling evaluation.

After 1993, Dr. Parisian was one of two Medical Officers in the Office of Device Evaluation, where she was primarily responsible for pre-marketing evaluation of new product applications and clinical trials that support safety and effectiveness leading to FDA approval, and where she conducted 100 health risk assessments.

In 1995, Dr. Parisian founded a consulting firm where she consults on topics regarding the FDA, pre-market clearance, design of clinical trials, product labeling, etc. In 1997, the FDA invited her to participate in a panel of experts convened to comment on changes proposed in requirements for medical device labeling. She has written a textbook entitled "FDA Inside and Out."

Plaintiffs offer Dr. Parisian to testify: 1) Baxter failed to satisfy its obligations to manufacture and market Heparin products that were safe, effective, adequately labeled, and in compliance with FDA regulations; 2) Baxter failed adequately to monitor and identify safety issues related to its Heparin products, timely report risks to the FDA, and warn healthcare providers and patients; 3) Baxter conducted delayed and flawed recalls of its Heparin products, minimized the attendant risks to patients and unnecessarily exposed patients to increased risk of contaminated Heparin; 4) Baxter failed to timely audit and verify the acceptability of SPL's manufacturing practices at its China based facility; and 5) SPL failed adequately to monitor the continued safety, efficacy and purity of Heparin API supplied to manufacturers and intended for use by American patients.

Defendants' motion seeks to exclude all of Dr. Parisian's opinions because, they claim, her opinions are "pure advocacy," unreliable and irrelevant and exceed the scope of her expertise.

First, Defendants contend Dr. Parisian is simply an advocate, not an expert. According to Defendants, Dr. Parisian has made a career out of being a high-paid expert witness exclusively for Plaintiffs.

Next, Defendants argue that Dr. Parisian's opinions are unreliable because they lack analysis and are nothing more than factual summaries and unsupported conclusions. Moreover, Defendants assert that her opinions are irrelevant because she merely presents a narrative summary that intrudes upon the jury's fact-finding duties. Defendants posit that Dr. Parisian will not be constrained by limiting instructions.[2]

Finally, Defendants argue that Dr. Parisian offers opinions beyond her expertise. Specifically, Defendants contend that Dr. Parisian will testify that contaminated Heparin causes and produces adverse reactions and deaths despite her admission that she is not a medical causation expert. Defendants also argue that Dr. Parisian's lack of knowledge in the field of analytical chemistry makes her unqualified to testify about the availability and efficacy of testing technologies to detect contamination in Heparin before OSCS was discovered in 2008.

Many courts, though sometimes limiting Dr. Parisian's opinions in some respects, have found her qualified to testify reliably about regulatory matters. Recently, my colleague Judge Dan Aaron Polster observed that, "Dr. Parisian is a regulatory expert who is qualified, based on her experience as a Medical Officer at the FDA and related experience thereafter, to offer testimony about regulatory requirements relating to the development, testing, marketing and post-marketing

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[2] I assure all counsel that I will take whatever steps I deem appropriate and necessary to restrain the not uncommon impulse of some witnesses, including some expert witnesses, to elaborate impermissibly on their answers. I remind counsel, though, that they need to carefully frame their questions so they do not invite such elaboration.

surveillance of prescription drugs." *In re Gadolinium-Based Contrast Agents Products Liab. Litig.*, *supra*, 2010 WL 1796334 at *13 (permitting Dr. Parisian to testify about pharmaceutical manufacturer's compliance with regulations but disallowing testimony in the form of a narrative history and regarding the intent, knowledge, motivations or purposes of the manufacturer, its employees and the FDA).

Judge Polster's opinion relied, in turn, on *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 190-93 (S.D.N.Y. 2009), finding Dr. Parisian qualified as a regulatory expert and allowing her to testify on regulatory requirements related to development, testing, marketing, and surveillance of prescription drugs. The court found Dr. Parisian demonstrated "specialized knowledge about the standards applicable to drug manufacturers." *Id.* In addition, the court, finding her methodology appropriate, also noted that Dr. Parisian's testimony would be helpful to a lay jury's understanding of the complex regulatory backdrop against which the events at issue played out. *Id*. at 190.

Defendants rely on *In re Traysol Prods. Liab. Litig.*, 2010 WL 1737107 (S.D. Fla.), in which the court found that Dr. Parisian's offered her opinions as a narrative and would discuss the "intent" of the company. *Id*. at *16-17. Plaintiffs assure the Court that her testimony will not be in a narrative fashion and that she will not express any views as to Defendants' intent, motives, or state of mind. .

As did the judges in *Gadolinium* and *Fosamax*, I find that Dr. Parisian is qualified as a regulatory expert based on her experience with the FDA and may offer testimony in regard to the development, testing, marketing and post-marketing surveillance of prescription drugs.

I also concur with those courts' findings that Dr. Parisian is not qualified to offer testimony as to medical or physiological causation issues. Although she is a medical doctor, she is not an

epidemiologist, immunologist, or hematologist, and therefore, does not have the necessary background and training to offer opinions concerning adverse reactions and deaths caused by contaminated Heparin.

Dr. Parisian's regulatory opinions are reliable, relevant and will assist the jury with understanding the complex regulatory framework and the standard of care applicable to pharmaceutical manufacturers. She bases her opinions on extensive, relevant experience with the FDA and her continued work as a consultant on regulatory issues.

As in *Fosamax* and *Gadolinium*, Dr. Parisian has applied the methodologies she employed as a Medical Officer.

Dr. Parisian may testify as to what:

- FDA regulations require;
- a manufacturer must do to comply with FDA regulations;
- could reasonably have been done to detect the presence of OSCS, including what testing methods were available to SPL but discontinued prior to the contamination of Heparin API; and
- Baxter should have or should not have done in light of applicable regulations, especially in regards to its recall processes, *i.e.* what must a manufacturer do to satisfy the standard of care established under the regulatory framework.

Dr. Parisian may not give a narrative history of Heparin contamination, which must be presented through direct evidence.

As with Dr. Siporin, Dr. Parisian may not offer "ultimate question" testimony that Baxter's monitoring, quality control measures, or recalls were ineffective or inadequate. Testimony

containing legal conclusions impermissibly "convey a witness' unexpressed, and perhaps erroneous legal standards to the jury." *U.S. v. Smith*, 2003 WL 21675340, *5 (6th Cir. July 15, 2003) (Unpublished disposition). "Moreover, testimony of an expert that constitutes mere personal belief as to the weight of the evidence invades the province of the jury." *Indiana Ins.Co. v. Gen. Elec. Co.*, 326 F. Supp. 2d 844, 847 (N.D. Ohio 2004). While Dr. Parisian may offer testimony concerning what a manufacturer should do to comply with regulations, she may not offer opinion testimony as to the reasonableness of the Defendants' conduct. Nor may she testify concerning the state of mind, intent, knowledge, purposes, or motivations of Defendants, its employees, or the FDA.

To the extent Defendants perceive a bias on her part against pharmaceutical manufacturers, Defendants can, and I assume will cross-examination her on that subject, which is not a basis for excluding her testimony. *See In re Unisys Savings Plan Litig.*, 173 F.3d 145, 166 n. 11 (3d Cir. 1999); *Ashburn v. Gen. Nutrition Ctrs., Inc.*, 2007 WL 4225493, *5 (N.D. Ohio).

Based on the foregoing, Defendants' motion shall be granted in part and denied in part.

3. Paul Midler

Paul Midler holds a Masters in Business Administration from the Wharton School of Business and a Masters Degree in International Business with a concentration in Chinese business from the University of Pennsylvania. Midler has lived and worked in China since 2002 and speaks fluent Mandarin. He is the founder of China Advantage, Ltd., a Hong Kong registered consulting firm providing third-party inspection and sourcing services to American companies in a variety of industries, including auto parts, home and garden supplies, personal care and beauty products, diamonds, toys, clothing, architectural hardware and construction supplies.

As a consultant, he acts as a liaison between Chinese suppliers and United States buyers by negotiating prices, evaluating suppliers, visiting and inspecting factories, and arranging testing of source material by third-party laboratories. Midler is the author of the book *Poorly Made in China*.

Plaintiffs desire to have Mr. Midler tell the jury that: 1) China is a risky place from which to acquire source materials, especially API; 2) the risks of sourcing materials in China include the risks of counterfeits and contaminants; 3) Baxter should have anticipated certain cultural phenomenon within the Chinese business environment, such as intentional counterfeiting, "quality fade," "savings culture," show and "shadow" factories and other manufacturing "games or tactics"; 4) these risks were well know and reasonably discoverable by any western company; 5) creation of a joint venture does not prevent or reduce these risks; 6) ACAS failed to insure its investment in China was made with a reliable partner and that operations and products made by the joint venture were safe and effective; 7) Baxter's one day inspection of its Chinese API manufacturer's facility almost four years after production had begun provided little protection; 8) Baxter should have established an impurity profile and analysis of the heparin molecule itself to ensure it was not contaminated or counterfeit; 9) in China, there are "open secrets" that result in a number of companies engaging in the same counterfeiting practices at the same time, and there were other Chinese Heparin consolidators or manufacturers of Heparin API that contained counterfeit molecules; 10) Baxter's failure to institute relevant testing, standards, impurity profiles, or other safeguards is inexcusable; 11) SPLs' discontinuance of purity testing for Baxter Heparin API, such as galactosamine testing it performed for other customers, is inexcusable; and 12) Defendants' actions and inactions showed a willful and flagrant disregard for the safety of patients and a reckless disregard for human life.

Midler claimed at deposition that he can "see beyond the facade in China" in a way that others cannot.

Defendants' motion seeks exclusion of Midler's opinions in their entirety on the basis that he is not qualified to render his opinions and his opinions are irrelevant, prejudicial and unreliable. Plaintiffs argue that Midler is qualified to offer his opinions based upon his professional background, education, review of depositions and exhibits, and years of professional experience in China; that his opinions are reliable and supported by his practical experience; and that his opinions are relevant to the issue of notice to Defendants about business conditions in China and are not unfairly prejudicial. Further, they assert that Midler "is the kind of manufacturing expert who appreciates that China is different and understands why it is different."

I find that Midler is not qualified to offer opinions about Chinese cultural norms, behavior and business conduct. He has no education or training as a cultural expert generally, or as an expert on Chinese culture specifically. Midler is not an expert in anthropology, sociology, history or ethnography and has had no training in any related academic fields "that might qualify one to provide reliable information about the cultural traits and behavior patterns of a particular group of people of a given ethnicity or nationality. *Jinro Am. Inc. v. Secure Investments, Inc.*, 266 F.3d 993, 1006 *opinion amended on denial of reh'g*, 272 F.3d 1289 (9th Cir. 2001) (excluding impressionistic generalizations about Korean businesses based on witness' personal investigative experiences, his "hobby" of studying Korean business practices, unspecified input from his office staff and his marriage to a Korean woman); *U.S. v. Urie*, 183 F. App'x. 608, 611 (9th Cir. 2006) (Unpublished disposition) (upholding lower court's exclusion of testimony on basis that witness' qualifications as

an expert were based only on the fact that he grew up in Nigeria and claimed to be "intimately familiar with Nigerian culture").

Midler likewise is not qualified to offer opinions concerning pharmaceutical drug or API manufacturing, testing, and quality control. He has no knowledge of FDA regulations or drug safety standards as they relate to the manufacture of prescription drugs and Heparin API in particular. He has never been hired by a pharmaceutical company and has no first-hand experience with the pharmaceutical industry. Neither does he have first-hand experience with companies in the supply chain leading to American pharmacies and patients. He has never inspected a pharmaceutical facility or performed or witnessed an audit of a drug API manufacturing factory.

Even if I were to find Midler qualified as an expert on Chinese business practices, Midler's opinions, as founded and presented here, are neither reliable nor relevant to the issues in this case.

An expert's methodology must be consistent with the "methods and procedures of science" rather than being founded on "subjective belief or unsupported speculation." Daubert, 509 U.S. at 592. Midler's opinions are not supported by an assessment of statistical data or a review of the work, findings and opinions of others. Midler's opinions with regard to the common practices of Chinese manufacturers and suppliers have not been tested or subjected to peer review or otherwise corroborated. At his deposition, Midler asserted that his conclusions are based on "common knowledge" and incapable of support by statistical data.

While this may be adequate support for a published book, *Daubert* demands that an expert must have "good grounds" for his beliefs. 509 U.S. at 590.

Midler's opinions are entirely personal, based on his own and, to be sure, relatively extensive, experience with a broad range of businesses in China. But Midler sees those experiences and the views they have created through the lens of subjectivity.

Even if he supported his opinions about other industries in China with objectively observable and reportable data, Midler has no basis to apply his opinions reliably to the pharmaceutical industry. He has no professional experience with pharmaceutical or API manufacturing outside of this litigation. Nor does he offer an adequate connection or link to the conduct of the parties in this case – nowhere does he explain how his observations about Chinese business practices relate to the Defendants.

In any event, I find that Midler's opinions are subject to exclusion pursuant to Fed. R. Evid 403. Whatever slight probative value his opinions might have is substantially outweighed by the risk of unfair prejudice. His generalized opinions about Chinese culture and business practice have no link to the parties involved in this case and have a serious risk of prejudicing the jury. Courts repeatedly exclude this type of testimony because "the risk of racial or ethnic stereotyping is substantial, appealing to bias, guilt by association and even xenophobia." *Jinro*, *supra*, 266 F.3d at 1008 (collecting cases). Accordingly, Defendants' motion shall be granted.

Conclusion

For the foregoing reasons, it is hereby

ORDERED THAT

1. Defendants' Motion to Exclude Expert Testimony of Dr. Clifford Siporin (Doc. 34) be, and the same hereby is, granted in part and denied in part;

2. Defendants' Motion to Exclude Expert Testimony of Dr. Suzanne Parisian (Doc. 38) be, and the same hereby is, granted in part and denied in part; and

3. Defendants' Motion to Exclude Expert Testimony of Paul Midler (Doc. 464) be, and the same hereby is, granted.

So ordered.

s/James G. Carr
United States District Judge